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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,025	04/24/2001	Judith Aronhime	1662/52602	6176
26646	7590	10/08/2004	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			HUANG, EVELYN MEI	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841,025

Applicant(s)

ARONHIME ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 161-166, 261, 262, 264-267, 269 and 271-279 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 161, 162, 261, 262, 264, 265 and 269 is/are allowed.
- 6) ☒ Claim(s) 163-166, 266, 267 and 271-279 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

1. Claims 161-166, 261, 262, 264-267, 269, 271-279 are pending. Claims 124-160, 167-260 have been canceled according to the amendment filed on 3-31-2003. Claims 263, 268, 270 have been canceled according to the amendment filed on 9-17-2004.

Withdrawal of Finality

2. In view of the following new grounds of rejection, the finality of the action mailed on 5-14-2004 is withdrawn.

Claim Rejections - 35 USC § 102

3. The rejection under 35 U.S.C. 102(b) as being anticipated by Benincasa (5891891, PTO-1449) is maintained for claims 165, and claims 273-279. The rejection is applicable to method claim 166.

Applicant submits that the prior art composition does not meet every requirement of the claimed invention wherein the zolpidem hemitartrate is zolpidem hemitartrate form D having a specific X-ray diffraction pattern in the form of particles.

Benincasa's pharmaceutical composition comprising Zolpidem hemitartrate (column 2, lines 15-25) would be the same as the instant liquid composition comprising a Zolpidem hemitartrate Form D hydrate or hemiethanolate in a particular size, since in a solution, the optionally micronized hydrate or hemiethanolate crystalline form of the instant zolpidem hemitartrate having a certain X-ray diffraction pattern no longer exist. The prior art composition therefore meet every requirement of the instant composition. Applicant has not set forth any facts to repute the above reasoning based on common knowledge.

Even if the composition were in a solid form, the novel crystalline structure of form D would no longer exist after the granulation, compaction or tableting process, as it is well known in the art that such process(es) would lead to alteration of the crystal structure (Chemical & Engineering News, February 2003, pages 33-34).

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The method of using the Zolpidem hemitartrate form D for treating insomnia is anticipated by the prior art method of treating insomnia with Zolpidem hemitartrate (column 2, lines 26-29) since in the in vivo physiological situation (which is mostly aqueous), the optionally micronized hydrate or hemiethanolate crystalline form of the instant zolpidem hemitartrate form D having a certain X-ray diffraction pattern no longer exist and would become identical to the the Zolpidem hemitartate of Benincasa.

Applicant contends that the Office Action ignores the fact that the composition claim 165 depends on the compound claim 161.

It is the examiner's position that the fact that claim 165 depends on claim 161 does not set a demarcation from the prior art composition for the reasons set forth above.

Claim Rejections - 35 USC § 112(1)

4. The written description rejection for Claims 161-166, 263-279 under 35 U.S.C. 112, first paragraph is withdrawn in view of the amendment obviating the rejection.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 264-267, 269, 271-272 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The 'monohydrate' of claims 264-267 or 'hemiethanolate' of claims 269, 271-272 has no antecedent basis in the base claim 161.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 163, 164, 266, 267, 271-278 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 163, 164, 266, 267, 271-278 are directed to particles of form D, and the pharmaceutical composition thereof. Since it is well known in the art that the granulation process(es) would lead to alteration of the crystal structure (Chemical & Engineering News, February 2003, pages 33-34), the Form D of different particles sizes would not be expected to have the same X-ray diffraction patterns as Form D. Indeed, micronized Form A has a different X-ray diffraction pattern than the non-micronized Form A in that there exist several unexpected peaks (page 36 of the specification, Example 34). Furthermore, different methods of micronization would result in different X-ray diffraction patterns, even for the micronized crystals having the same size (Bernini, 4332721). However, an example of micronized Form D has not been prepared and the X-ray diffraction of the micronized Form D has not been shown, without which one of ordinary skill in the art therefore would not be able to make the invention as claimed without undue experimentation.

Allowable Subject Matter

7. Claims 161, 162, 261, 262, 264, 265, 269 are allowed.

While Zolpidem hemitartrate in the form of hydrate or solvate is described by Ettema I and II, Form D with the specific X-ray powder diffraction pattern as recited in the instant claims is not taught or suggested by the prior art of record.

Drawings

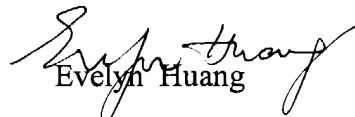
8. The submission of corrected drawings is acknowledged.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Evelyn Huang

Primary Examiner

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